

The spreadsheets attached to this document were prepared by the Innovative Therapies for Childhood Cancer Sponsor Institution Committee in 2015 and are reproduced here with their kind permission.

# ITCC INTERNATIONAL CLINICAL TRIALS INSURANCE SPREADSHEET



Innovative Therapies for Childhood Cancer (ITCC [www.itccconsortium.org](http://www.itccconsortium.org)) is an international consortium comprising a network of 49 non-commercial institutions in 8 countries dedicated to delivering excellent trials in children's cancers. Within this Consortium, following a call for expression of interest and an independent peer review process, the ITCC established a network of institutions with expertise and capabilities in delivery of European sponsorship for multi-country early phase clinical trials for childhood and adolescent cancers, as well as a network of institutions with expertise and capabilities to coordinate their country's network of ITCC sites and deliver delegated sponsor activities.

The ITCC Sponsor Institution Committee (chaired by Prof. Pam Kearns, CRCTU, UoB) has collaborated to develop several agreed trial templates and guidance documents to facilitate and expedite the set up and delivery of multi-country clinical trials conducted within the network. One work-package focussed on the national differences in clinical trials insurance requirements (led by Dr Sean Jennings, UoB) and generated a clinical trials insurance spreadsheet.

The ITCC clinical trials insurance spreadsheet is offered as a means of sharing information gathered by ITCC Sponsor Institution Committee in order to support in identifying the insurance requirements for their trials.

The survey questions on the left of the spread sheet were circulated to ITCC member institutions with a request that they be completed by the person at the institution responsible for clinical trials insurance (rather than, e.g. by investigators).

The questions were developed by the insurance and legal specialists at ITCC Sponsor institutions as a way of getting initial information about what the insurance requirements (and possibilities) in each country are. We expect that these questions might be useful to other Sponsors and trials teams setting up international clinical trials.

We have also included responses to the questionnaires. We have found these useful both in negotiating contracts with partner institutions and in negotiating with insurers.

Please note:

- **Nothing in this spreadsheet or document constitutes legal or professional advice concerning your insurance requirements.**
- **While the responses from particular institutions will be indicative, they should not be taken as authoritative assessments of the insurance requirements for a particular country.**
- **The spreadsheet has not been updated since July 2015.**